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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,848	04/09/2004	Lawrence V. Tannenbaum	CHPPM 03-22 03	8673
27370 7590 02/14/2008 OFFICE OF THE STAFF JUDGE ADVOCATE U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND ATTN: MCMR-JA (MS. ELIZABETH ARWINE) 504 SCOTT STREET FORT DETRICK, MD 21702-5012			EXAMINER LIN, JERRY	
			ART UNIT 1631	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,848

Applicant(s)

TANNENBAUM, LAWRENCE V.

Examiner

Jerry Lin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-12 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) 7-12, 14 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 15, 16 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 6, 2007 has been entered.

Status of the Claims

Claims 1-3, 5, 6, 15, 16, and 18-23 are under examination.

Claims 7-12, 14, and 17 are withdrawn as being drawn to a non-elected invention or species. (The Examiners acknowledges that claims 7-12, 14, and 17 may be rejoined upon allowance of the generic claims).

Specification

2. The use of the trademark HAMILTON-THORNE IVOS SPERM ANALYZER has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Please capitalize all trademarks.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3, 5, 6, 15, 16, and 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 18, and 22 are indefinite, because it is unclear what data is used for determining the health of mammals or assessing ecological risk. Claims 1, 18, and 22 each recite comparing sperm count, sperm motility, or sperm morphology of the rodents. However, the instant claims do not indicate that the comparison of sperm count, sperm motility or sperm morphology is used for the determination of mammal health or ecological risk uses. Rather, the instant claims only recite that a determination or assessment is made without any indication of what that determination or assessment is based upon. Thus it is unclear what data is used for determining the health of mammals or assessing ecological risk. Instant claims 2, 3, 5, 6, 15, 16, 19-21, and 23 are also rejected for depending from claims 1, 18, and 22.

Claim 23 is indefinite because it is unclear how the comparison of organ-to-body weigh ratios contributes to the overall method of determining potential health risks to mammals. New claim 23 recites comparing organ-to-body weight ratios between rodents from a contaminated site and rodents from a reference site. However, this

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comparison is never used for the determination of potential health risks. Thus, it is unclear how claim 23 contributes to the overall method.

Claim Rejections - 35 USC § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1-3, 5, 6, 15, 16, and 18-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining the ecological risk to rodents, does not reasonably provide enablement for determining the ecological risk to other animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of assessing ecological risk for mammals by performing sperm analysis on rodents from a contaminated site and a reference site and comparing the results of the rodents from the different sites, where if the results exceeds a benchmark, the rodents have impaired reproductive capability and assessing the ecological risk to animals at the contaminated site. For purposes of this rejection, the Examiner interprets the instant claims to mean that the determination or assessment is based upon the comparison of sperm count, sperm motility or sperm morphology.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include:

- (1) the quantity of experimentation necessary – since it is unknown whether the ecological risk to mice may be extrapolated to other mammals, a great deal of experimentation is needed.
- (2) the amount of direction presented – the specification focuses on mice, but does not derive data from other mammals or teach how the data from mice applies to other mammals.
- (3) the presence or absence of working examples – there are no working examples of data from mammals other than rodents.
- (4) the nature of the invention – the invention is drawn to assessing how mammals will react to a contaminated site. How an organism will react to environmental changes is unpredictable.
- (5) the state of the prior art – the prior art does not show how the data from mice may be extrapolated to other mammals.
- (6) the relative skill of those in the art – the level of skill of those in the art is high.
- (7) the predictability or unpredictability of the art – extrapolating the results of one mammal to another different mammal is unpredictable.

(8) the breadth of the claims – the instant claims are drawn to assessing the ecological risk to animals.

The preamble and the final step of the independent claims, claims 1, 18, and 22 recite that the method assesses the ecological risk to mammals or determining the potential health effect to mammals. Giving the word “mammals” a broad reading, the claimed method determines the ecological risk to mammals other than rodents. However, the method only examines data derived from rodents. While it is clear that there the claimed method may measure the ecological risk to rodents, the method may not measure the ecological risk to other animals. According to Working, factors such as genetic variability, metabolism, intracellular pathways of toxicity, membrane biochemistry, absorption, distribution, storage, excretion, and specific organ function all contribute to major variability in responses to toxic chemicals (page 37, left column – page 38). In particular, Working states that the fertility of animal models may be an insensitive indicator of human reproductive risk (page 38, left column). The instant specification does not provide any data or rationale of why determining the ecological risk to mice may be extrapolated to assess the ecological risk to other mammals. Thus in order to determine the ecological risk to other mammals, one of ordinary skill in the art must perform undue experimentation.

Response to Arguments

7. The Applicant first responds to this rejection by stating that rodents burrow in the contaminated soil, eat contaminated vegetation, and drink contaminated water, typically

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do not migrate, and many generations of rodents live in contaminated areas year after year. The Applicant then states that one can reason that if rodents are not experiencing reproductive impacts, other mammals are also not experiencing compromised reproductive success. However, not all mammals have the same degree of contact with contaminated soil, vegetation, and water, or have the same behavioral patterns when it comes to migration and habitation. For example, deer do not burrow, but they do migrate and each generation may travel to a different location. Thus, if a rodent is experiencing a reproductive impact, deer may not be experiencing a reproductive impact. Not all mammals may be as sensitive to the environment as rodents, and thus the ecological risk to rodents cannot be extrapolated to other mammals.

While the Examiner agrees that rodents are often used to determine contamination in the environment as stated in Phillips et al., it is also well known that a rodent model may not be accurately extrapolated to other animals. For example, Working states that the fertility of animals models may be an insensitive indicator of human reproductive risk (page 38). Similarly, contaminants in the soil may have an impact on rodents, but have no impact on larger and wider ranging mammals that do not burrow in the soil.

This rejection is maintained from the previous office action.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3, 5, 6, 18, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ieradi et al. (Folia Zoologica (January 2003) Volume 52, Number 1, pages 57-66) in light of Ryabokon et al. (Radiat. Environ. Biophys (2005) Volume 44, pages 169-181) in view of Sharma et al. (Reproductive Toxicology (1996) Volume 10, number 2, pages 153-159).

The instant claims are drawn to a method for assessing the risk to mammals by obtaining mice from a contaminated site and a reference site, performing sperm analysis on the mice including sperm count, comparing the sperm analysis of the mice from the reference site to the sperm analysis of the mice from the contaminated site, and determining if the comparison exceeds one or more sperm parameter benchmarks, where if the results exceeds a benchmark, the rodents have impaired reproductive capability and assessing the ecological risk to animals at the contaminated site. (It is noted that on page 9 of the specification, at paragraph 0047, the process of determining if sperm parameters have exceeded a sperm parameter benchmark or threshold-for-effect are accomplished by comparing sperm parameter values of the rodents of the contaminated site and reference site using statistical techniques such as pair-wise statistical comparisons or the Wilcoxon rank sum test).

Regarding claims 1-3, 6 and 22, Ieradi et al. teaches a method for assessing the ecological risk to mammals that includes obtaining a representative sample of mice from a contaminated site (page 58, bottom – page 59, top) where the mice reflect

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generations of exposure to the contaminated site (Ieradi et al. states that the rodents were trapped in 1995 and 1996 (page 58, bottom). Ryabokon et al. states that trapping *A. flavicollis*, the yellow necked mouse, a year later would consist of individuals born at least two generations after the initial trapping (page 176, left column)); obtaining mice from an animal reference site (page 58, bottom – page 59, top); performing sperm analysis on both sets of rodents such as sperm abnormality (page 59, last full paragraph); comparing the results from both sets of mice (page 62) ; and determining if the comparison between results from both sets of mice exceeds a sperm parameter benchmark or thresholds-for-effect (i.e., a statistical test of significance) (page 62) for assessing ecological risk to mice (such as lost of spleen function) (abstract; page 61).

However, Ieradi et al. do not teach where the sperm analysis includes measuring sperm count, and where if the sperm parameter benchmark is exceeded, the mice have impaired reproductive capability and assessing the ecological risk to mice at the contaminated site.

Regarding claims 1, 5, 18, 22 and 23, Sharma et al. teach a method of determining the toxicity of a chemical in mice by removing the vas deferens and epididymis to assess sperm count and motility (abstract; page 156) and determining if the comparison of control to the test group was statistically significant (exceeded a sperm parameter thresholds-for-effect) (page 156). Sharma et al. teach that the mating rate was reduced to zero (impaired reproductive capability) in mice in the test group (page 156, left column). Sharma et al. also teaches comparing organ to body weight ratios of the rodents from the contaminated site with rodents from the reference site

(i.e., calculating the relative weights of the organs with respect to the whole body weights) (page 157, left column).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the methods of Ieradi et al. and Sharma et al. Ieradi et al. and Sharma et al. are both concerned with the effects of environmental pollution on human and animal systems (abstract of both). In particular they are concerned with metals. Ieradi et al. states that wild mice are useful as bioindicators to detect local contamination (page 64). Given that Sharma et al. are concerned with determining that toxic effects of mercury in animal systems (page 153, left column), one of ordinary skill in the art would have sought to use a known bioindicator to detect the local contamination of mercury at a particular site. Thus one of ordinary skill in the art would have been motivated to combine the methods of Ieradi et al. and Sharma et al. to trap wild mice and conduct the sperm analysis suggested by Ieradi et al. and Sharma et al. to determine the pollution at a site.

Response to Arguments

10. The Applicant has responded to Sharma et al. as it was used in a previous rejection under 35 U.S.C. §103 with a different reference. Although, the instant rejection is a new rejection using a new reference, the Examiner will address those arguments that applied to Sharma et al.

The Applicant first states that Sharma et al. does not disclose correlating lab-imposed mercury effects to ecological risk to animals at a contaminated site using impaired reproductive capability. The Examiner disagrees. Sharma et al. teach that the

group with the lower sperm count and impaired sperm mobility also has a mating rate (impaired reproductive capability) of zero (page 156). Furthermore, impaired reproductive capability is a type of ecological risk to mice. Thus, Sharma et al. do teach the mercury effects to ecological risk to mice using impaired capability.

While the Examiner agrees that Sharma et al. does not use their method for a contaminated site, the combination of Sharma et al. and Ieradi et al. demonstrates that it would have been obvious for one of ordinary skill in the art to use Sharma et al.'s method at a contaminated site.

Finally, the Applicant states that the Examiner has not provided the same motivation as the claimed invention. However, the motivation for a rejection under 35 U.S.C. §103 need not be the same as the Applicant's motivation.

11. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ieradi et al. (Folia Zoologica (January 2003) Volume 52, Number 1, pages 57-66) in view of Sharma et al. (Reproductive Toxicology (1996) Volume 10, number 2, pages 153-159) as applied to claims 1-3, 5, 6, 18, 22, and 23 above, and further in view of Phillips et al. (Federal Facilities Environmental Journal (2002) Volume 13, Issue 1, pages 7-25) in light of Ryabokon et al. (Radiat. Environ. Biophys (2005) Volume 44, pages 169-181).

The instant claims are drawn to a method for assessing the risk to mammals by obtaining mice from a contaminated site and a reference site, performing sperm analysis on the mice including sperm count, comparing the sperm analysis of the mice

from the reference site to the sperm analysis of the mice from the contaminated site, and determining if the comparison exceeds one or more sperm parameter benchmarks, where if the results exceeds a benchmark, the rodents have impaired reproductive capability and assessing the ecological risk to animals at the contaminated site. In particular the instant claims contain embodiments where the site is contaminated with explosive or that the mice represent one hundred generations of exposure.

Ieradi et al. and Sharma et al. are applied as above.

However, neither Ieradi et al. nor Sharma et al. teach that a contaminated site may be contaminated with explosives.

Regarding claim 15, Phillips et al. teach collecting rodents (i.e. mice) from a contaminated site that may be contaminated with explosives (page 13, bottom).

Regarding claim 16, Phillips et al. teach that the sites have been exposed to explosives for 84 or 55 years (page 8). Given the short life span of mice (See Ryabokon et al. page 176, left column), the mice trapped at these locations would reflect one hundred generations of exposure.

It would have been obvious for one of ordinary skill in the art at the time of the invention to collect mice from a contaminated site with explosives, such as Phillips et al., and to use the methods of Ieradi et al. and Sharma et al. to determine the effects of contamination by explosives on mice. Ieradi et al., Sharma et al., and Phillips et al. are all concerned with the effects of environmental pollution on human and animal systems (abstract of each reference). Phillips et al. teaches that analyzing the ecological risk to humans and animals at sites contaminated with explosives is desirable to identify

potential hazards (abstract). leradi et al. teach that their method helps determine the environmental effects on a mice (abstract). Thus, one of ordinary skill in the art would have been motivated to use the mice from the sites disclosed by Phillips et al. and apply the methods of leradi et al. and Sharma et al. to determine the ecological risks at these contaminated sites.

Response to Arguments

12. The Applicant has responded to Phillips et al. as it was used in a previous rejection under 35 U.S.C. §103 with a set of different references. Although, the instant rejection is a new rejection using a new reference, the Examiner will address those arguments that applied to Phillips et al.

Applicant state that because Phillips et al. did not find explosives in the tissues of the rodents, rodents are not bioindicators for explosives or metals. The Examiner disagrees. Phillips states that because they did not find explosives or metals in rodents that "these studies present scientific data to support the argument that firing high-explosive munitions in both a dry desert and humid temperature climate (as a form of military land use) is a relatively clean industry." (page 23) Phillips et al. can make this claim because rodents are bioindicators for explosives or metals. Since they are bioindicators, one of ordinary skill in the art would use mice to determine if a site was contaminated.

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over leradi et al. (Folia Zoologica (January 2003) Volume 52, Number 1, pages 57-66) in view of

Sharma et al. (Reproductive Toxicology (1996) Volume 10, number 2, pages 153-159) as applied to claim 1-3, 5, 6, 18, 22, and 23 above, and further in view of Working (Environmental Health Perspectives (1988) Volume 77, pages 37-44).

The instant claims are drawn to a method for assessing the risk to mammals by obtaining mice from a contaminated site and a reference site, performing sperm analysis on the mice including sperm count, comparing the sperm analysis of the mice from the reference site to the sperm analysis of the mice from the contaminated site, and determining if the comparison exceeds one or more sperm parameter benchmarks, where if the results exceeds a benchmark, the rodents have impaired reproductive capability and assessing the ecological risk to animals at the contaminated site. In particular, the instant claim contains an embodiment where the benchmark is a 80%-90% decrease in sperm count.

Ieradi et al. and Sharma et al. are applied as above.

However, neither Ieradi et al. nor Sharma et al. teach that an 80% to 90% decrease in sperm count indicates compromised reproductive success.

Working teach that a 90% decrease in sperm count indicates compromised reproductive success (page 38, left column bottom).

It would have been obvious for one of ordinary skill in the art at the time of the invention to use the criteria of Working with the methods of Ieradi et al. and Sharma et al. to determine the effects of pollution on mice. Ieradi et al. and Sharma et al. are both concerned with the effects of environmental pollution on human and animal systems (abstract of both). Environmental pollution often affects an animal's ability to reproduce.

Thus one of ordinary skill in the art would be motivated to use the criteria of Working in order to determine if the rodents obtained by leradi et al. had a compromised reproductive system because of sperm count.

14. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over leradi et al. (*Folia Zoologica* (January 2003) Volume 52, Number 1, pages 57-66) in view of Sharma et al. (*Reproductive Toxicology* (1996) Volume 10, number 2, pages 153-159) as applied to claim 1-3, 5, 6, 18, 22, and 23 above, and further in view of Chapin et al. (Applicant's IDS #2).

The instant claims are drawn to a method for assessing the risk to mammals by obtaining mice from a contaminated site and a reference site, performing sperm analysis on the mice including sperm count, comparing the sperm analysis of the mice from the reference site to the sperm analysis of the mice from the contaminated site, and determining if the comparison exceeds one or more sperm parameter benchmarks, where if the results exceeds a benchmark, the rodents have impaired reproductive capability and assessing the ecological risk to animals at the contaminated site. In particular, the instant claim contains an embodiments where the benchmark is a 40%-50% decrease in sperm motility or an increase of 4% or more of abnormally shaped sperm.

leradi et al. and Sharma et al. are applied as above.

However, neither leradi et al. nor Sharma et al. teach that a decrease of about 40%-50% in sperm motility or an increase of 4% or more of abnormally shaped sperm indicates compromised reproductive success.

Chapin et al. that a decrease of about 40%-50% in sperm motility or an increase of 4% or more of abnormally shaped sperm indicates compromised reproductive success (abstract; page 131, left column, bottom; page 131, right column, 2nd full paragraph).

It would have been obvious for one of ordinary skill in the art at the time of the invention to use the criteria of Chapin et al. with the methods of leradi et al. and Sharma et al. to determine the effects of pollution on mice. leradi et al. and Sharma et al. are both concerned with the effects of environmental pollution on human and animal systems (abstract of both). Environmental pollution often affects an animal's ability to reproduce. Thus one of ordinary skill in the art would be motivated to used the criteria of Chapin et al. in order to determine if the rodents obtained by leradi et al. had a compromised reproductive system because of sperm motility or abnormally shaped sperm.

Response to Arguments

15. The Applicant has responded to Chapin et al. as it was used in a previous rejection under 35 U.S.C. §103 with a set of different references. Although, the instant rejection is a new rejection using a new reference, the Examiner will address those arguments that applied to Chapin et al.

The Applicant first responds by stating that Chapin et al. does not teach using mice as bioindicators for the presence of other chemicals and examining the toxic effects. The Examiner agrees. However, the Examiner is not relying on Chapin et al. to teach using mice as bioindicators for the presence of other chemicals and examining the toxic effects. Rather, the Examiner is relying on Chapin et al. to teach a decrease of about 40%-50% in sperm motility or an increase of 4% or more of abnormally shaped sperm indicates compromised reproductive success.

Withdrawn Rejections

16. Applicant's arguments and amendments, filed 11/6/2007, with respect to the rejection made under 35 U.S.C §102(b) as being anticipated by Ieradi et al. (Environmental Pollution (1996) Volume 92, number 3, pages 323-328) have been fully considered and are persuasive, because the instant reference does not teach where the rodent reflect generations of exposure or where the sperm analysis includes measuring sperm count. Furthermore, the reference Meistrich et al. (Applicant's IDS #4) has been withdrawn from the rejection made under 35 U.S.C. §103 because the reference does not teach that an 80% to 90% decrease in sperm count indicates compromised reproductive success. These references have been withdrawn.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/
Examiner, AU 1631
2/1/2008